Section IV: 510k Summary

FEB 1 4 2013

Applicant's Identification

Applicant	Grandway Technology (Shenzhen) Limited
Phone Number	(00852)-2851-6789
Fax Number	(00852)-2851-6278
Contact Person	Mr. Patrick Chow
Date of Application	24th Feb, 2012

Device's Identification

Device Proprietary Name: Digital Automatic Blood Pressure Monitor BPM11 Series

Model No.: MD11xy

x --- The first character (0, 1, 3, 5, 6 or 8) is for the minor change revision of device. The mentioned "minor change" refers to those device changes not to be affected the conformity test results of EMC & safety as well as device performance, i.e. IEC 60601-1 and EN 60601-1-2.

y --- The second character (which is always 0) is for the identification of cabinet (housing).

Common Name	Non-invasive Blood Pressure Measurement System
Classification Name	Non-invasive Blood Pressure Measurement System (Class II per 21 CFR 870.1130)

Marketed Devices to which Equivalence is Claimed

DEVICE	MANUFACTURER	510(k) Number
AViTA BPM6 Series Blood Pressure Meter (or Monitor)	AViTA Corp	K033397

Device Description

Digital Automatic Blood Pressure Monitor BPM11 Series is a non-invasive blood pressure measurement system for use by medical professional or at home. It is designed to measure the systolic and diastolic blood pressure, and pulse rate (heartbeat rate) of an individual in each measurement and then displays the readings on a digital panel.

The BPM11 Series utilizes the oscillometric methodology, in which an inflatable cuff is wrapped around the upper arm of an individual, for the blood pressure measurement. This means the monitor detects your blood's movement through your brachial artery and converts the movements into a digital reading.

Intended Use (Indication for Use)

Digital Automatic Blood Pressure Monitor BPM11 Series is for use by medical professional or at home. The BPM11 Series is intended to measure the systolic and diastolic blood pressure, and pulse rate (heartbeat rate) of an individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the upper arm of an individual. The inflatable cuff circumference is limited to 17cm – 44cm via 3 different size of cuff. 3 different cuff sizes are 17-22cm, 22-32cm and 32-44cm.

Comparison of Technological Characteristics between New Device and Predicate Devices

The Digital Automatic Blood Pressure Monitor BPM11 Series is a non-invasive measuring device and utilizes the oscilliometric methodology to measure the blood pressure reading. The key components of device are a pressure sensor, electric valve and an electronic control module together with an electric pump, which inflate (and deflate) the inflatable cuff automatically according to our designed architecture. The predicate device adopts exactly same methodology and key components for measuring the blood pressure reading.

Clinical & Non-clinical Tests

A systematic & independent clinical test was conducted to validate the performance of the Digital Automatic Blood Pressure Monitor BPM11 Series. The results demonstrated that BPM11 Series meets the requirement of ANSI/AAMI SP-10-2002.

Comprehensive safety and EMC tests were performed and compiled to demonstrate BPM11 Series is safe for use. Tests include
EN1060-1:1995/A2:2009
EN1060-3:1997/A2:2009
IEC60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007)
EN60601-1-2:2007
FCC Part 15
ISO10993-5:2009
ISO10993-10:2002 + A1:2006
EN60601-1-4:2007

Conclusion

Digital Automatic Blood Pressure Monitor BPM11 Series has the same intended use and similar technological characteristics as predicate device (K033397). Moreover, bench testing contained in this submission and clinical testing supplied demonstrated that no differences in the technological characteristics and questioning on safety or effectiveness to be raised. Thus, the Digital Automatic Blood Pressure Monitor BPM11 Series is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 14, 2013

Grandway Technology (Shenzhen) Limited
c/o Mr. Patrick Chow, General Manager
Block 6 and 7, Zhu Keng Industrial Zone, Ping Shan
Long Gang District
Shenzhen, Guang Dong
People's Republic of China

Re: K120675
Trade/Device Names: Digital Automatic Blood Pressure Monitor with models MD1100, MD1110, MD1130, MD1150, MD1160 and MD1180
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: February 6, 2013
Received: February 8, 2013

Dear Mr. Chow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section V: Statement of Indications for Use

510(k) Number (if known): K120675

Device Name:

Digital Automatic Blood Pressure Monitor BPM11Series

Model No.: MD11xy

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Prescription Use _____ AND/OR Over-The-Counter Use_X_____
(Part 21CFR 801Subpart D) (21CFR 801Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S